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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/664,423 | 09/17/2003 | Guy A. Rouleau | GOUD:023USD2 | 3952 |

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| EXAMINER | |
|---|---|
| KOLKER, DANIEL E | |
| **ART UNIT** | **PAPER NUMBER** |
| 1649 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 03/30/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/664,423 | ROULEAU ET AL. | |
| | Examiner | Art Unit | |
| | Daniel Kolker | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *14-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/16/06,1/29/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Attachment: sequence alignments.

## DETAILED ACTION

1. The remarks and amendments filed 22 December 2006 have been entered. Claims 14 – 29 are pending and under examination. The amendments to the specification have been entered as they merely correct typographical errors and introduce no new matter.

### *Information Disclosure Statement*

2. The information disclosure statement filed 16 October 2006 has been considered. Two references have been crossed off the IDS.

Reference C77 has been crossed off. Applicant has not submitted the complete sequences of the two referenced GenBank accession numbers. What has been submitted is a partial printout of an alignment between one of the sequences (AF035685) and SEQ ID NO:65 from 10/664422. However note that the entire alignment is not enclosed; the end of page 2 indicates that certain bases appear on the next page. Also note that no data have been submitted with respect to AF035686.

Applicant is advised that reference C78, cited on the IDS filed 16 October 2006, has been crossed off because it is duplicative. Note the reference was cited by the examiner on form 892 mailed with the office action of 22 August 2006. Thus the reference would appear on the face of a patent, should one issue from this application.

The information disclosure statement filed 29 January 2007 has been considered. Two references have been crossed off the IDS.

Entry C79 has been amended by the examiner to indicate that only a single page has been received, as opposed to 774 pages as written by applicant. The examiner is unable to determine the contents of the book referred to in the citation as it has not been submitted. Should applicant desire particular articles or chapters from the book to be considered by the examiner, applicant may of course submit them.

Entry C81, entitled "BLAST result" has been crossed off the IDS. A single sheet was submitted indicating that two sequences were compared and that no significant similarity was found. A handwritten note on the page is difficult to read. It is unclear whether the sequences compared were SEQ ID NO:12 and 13, or whether they were SEQ ID NO:72 and 73. Furthermore, the submitted document does not indicate the actual sequences that were submitted to the BLAST website, nor does it indicate when those sequences were published. The examiner is thus unable to determine what comparison was performed. Finally, as neither

SEQ ID NO:12, 13, 72, or 73 is being claimed herein, it is not immediately obvious how the comparison is germane to patentability or examination. Should applicant desire particular accession numbers of particular databases be considered by the examiner, applicant may of course submit them.

***Withdrawn Rejections and Objections***

3. The objections to the claims for reciting non-elected subject matter are withdrawn in light of the amendments.

4. The rejection of claims 20 – 22 under 35 USC § 101 for being directed to non-elected subject matter is withdrawn in light the amendments which narrow the claims to isolated cells.

***Maintained Rejections and Objections***

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 – 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid sequence of SEQ ID NO:1, or for those specific mutations set forth in claims 25 – 28, does not reasonably provide enablement for all complements as broadly set forth in claim 14, or for all fragments or variants encompassed by claims 14 – 16, or for all nucleic acids which have only 119 contiguous bases of SEQ ID NO:1, as recited in claim 29. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained with respect to claims 14 – 22 and extended to new claims 23 – 29 as explained below. Applicant is referred to the office action mailed 22 August 2006 for a more complete description of why claims that encompass fragments, derivatives, and allelic variants are not completely enabled. Briefly, the claims are sufficiently broad that they do not require any particular structural element to be present. Claims to products which are "allelic variants" of disclosed sequences cannot be made by the skilled artisan, because the specification does not disclose to the artisan what the structure of the full scope of those

variants is. While certain variants are disclosed at p. 52 of the specification, what is actually enabled by the specification is relatively narrow, whereas what is claimed is very broad, in that it encompasses any allelic variant, including those not yet disclosed. The specification does not show which regions are common to all allelic variants, nor does it disclose any particular required degree of identity to a disclosed sequence. Furthermore, fragments and functional derivatives which retain "a biological function of an alpha subunit of a sodium channel", as recited in claim 15 are not reasonably enabled over their full scope. While certain biological activities are defined in the specification, the definition of biological activity set forth on p. 19 line 20 of the specification is not limited to any particular function. The definition is quite clearly inclusive, but not limiting. Thus the broadest reasonable interpretation of "biological activity" includes the ability to raise antibodies, in the case of proteins, or even the ability to modulate osmotic pressure across a semipermeable membrane, a biological function which can be provided by any molecule of sufficient size. The specification does not set forth how to use all the molecules within the scope of the claims, as it only discusses nucleic acids which encode sodium channels.

Additionally, claim 14 now encompasses any complement of SEQ ID NO:1, no matter the size. There is no requirement that "a complement" as claimed be able to have any function on its own, nor is there any requirement that the claimed nucleic acid molecules encode any particular amino acid sequence themselves. Thus the broadest reasonable interpretation of claim 14, part (b), includes nucleic acids which are complementary over very short stretches of SEQ ID NO:1. The specification does not teach the public how to use these complements. Note that the same "complement" language also appears in claim 29. If applicant intends to only claim those molecules which are complementary to SEQ ID NO:1 over its entire length, it is recommended that applicant amend the claims to recite language such as "a full-length complement of SEQ ID NO:1", provided there is sufficient basis in the specification.

Claim 29, newly added by amendment, does not require that the encoded protein have any particular function. While the claim does state "encoding an alpha subunit of a sodium channel", the claim also only requires that 119 nucleotides be present. As SEQ ID NO:1 encodes an alpha subunit but is over 8000 bases long, it is not immediately apparent how something as small as 119 nucleotides will in fact have the same function. The specification does not disclose to the public how to use nucleic acids only 119 bases long, as these would only encode 39 amino acids.

Thus given the breadth of the claims, the lack of disclosure in the specification commensurate with this broad scope, and the fact that the claims encompass an unreasonably large number of products which the specification does not disclose how to use, the skilled artisan would essentially have to discover how to use these products by himself. Given the lack of adequate guidance commensurate in scope with what is claimed, the artisan would have to resort to an undue amount of experimentation in order to determine how to make and how to use the full scope of the products encompassed by these claims.

6. Claims 14 – 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

This rejection is maintained with respect to claims 14 – 22 for the reasons of record and extended to newly-added claims 23 – 28 as they all depend, either directly or ultimately, from claim 14. Briefly, while the specification does disclose a very few allelic variants, the genus of allelic variants as a whole cannot reasonably be considered to be described. There is no identification of what structural elements are common to all variants, nor is there any indication as to which nucleic acids can be changed between said variants. Similarly, there is no description of what constitutes a fragment or functional derivative, as recited in claims 15 – 16. The specification does not disclose to the artisan which regions of SEQ ID NO:1 must be maintained such that the resulting protein has "a biological function of an alpha subunit of a sodium channel" as recited in claims 15 – 16. The skilled artisan cannot visualize the genus of sequences or chemical compounds claimed, because the specification does not describe them.

Furthermore new claim 24 encompasses any and all nucleic acids within the scope of claim 14 which are "associated with an increased susceptibility to idiopathic generalized epilepsy". The specification points out allelic variants within this broad genus, but does not indicate which structural elements are common to all members of the genus. There is no disclosure of the length or sequence identity compared to SEQ ID NO:1 which is required for the generic variant. The specification fails to disclose the full genus, and the skilled artisan could not determine what shape, structure, or sequence these nucleic acids or their encoded proteins have. The specification does not disclose to the public which particular variants are associated

with all forms of idiopathic generalized epilepsy. As such, the full scope of the genus of claims 14 and 25 is not supported by the specification.

Applicant argues, on p. 10 of the remarks, that claim 14 is limited to nucleic acids at least 95% identical to SEQ ID NO:1. This may be applicant's intent, but the broadest reasonable interpretation of claim 14 includes any nucleic acid, independent of length, that is complementary to any section of SEQ ID NO:1. Furthermore, claim 15 encompasses any fragment of SEQ ID NO:1. While claim 15 depends from claim 14, since the products of claim 14 are not limited by any particular length, neither are those of dependent claims. Clearly the full genus of fragments, functional derivatives, allelic variants, and complements has not been described in the specification.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14 – 24 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Mandel (WO 96/14077), as evidenced by Mandel (U.S. Patent 6,10,672).

This rejection stands with respect to claims 14 – 22 for the reasons of record and is extended to claims 23 – 24 and 29 as explained herein. Briefly, Mandel teaches SEQ ID NO:14 which shares several regions of identity with instant SEQ ID NO:1, as well as vectors and host cells comprising the nucleic acid. The claims have been amended to include "a complement of" SEQ ID NO:1 (claim 14) and nucleic acids encoding fragments of alpha subunits that retain "a biological function" (claims 15 – 16). The broadest reasonable interpretation of "a complement" includes any nucleic acid which is complementary to any part of SEQ ID NO:1. Note there is no requirement in claim 14, part (b), that the claimed complement be of any particular length or that it be complementary over the full-length of SEQ ID NO:1. As claims 14 and 29 encompass any nucleic acid comprising any complement of SEQ ID NO:1, and the reference by Mandel clearly teaches double-stranded DNAs (see for example WO 96/14077, pages 9 – 11), the reference anticipates claims 14 and 29. Furthermore it is noted that the reference by Mandel is on point to sodium channels, thus it would appear that the prior art nucleic acids have sodium channel

activity in particular, and even in the case that they do not, the nucleic acids reasonably have "a biological function" of a sodium channel as the nucleic acids are inherently capable of modulating osmotic pressure across a semipermeable membrane, which is a biological function. Thus the nucleic acids which comprise fragments which have biological activity, anticipating claims 15 – 16 and sodium channel activity, anticipating new claim 23. Claims 17 – 22 are rejected as Mandel teaches both vectors and host cells. Claim 24 is rejected as it depends from claim 14 and has no additional structural requirements. Absent evidence to the contrary, the "associated with" limitation appears to be provided for.

Applicant argues, on p. 11 of the remarks, that the nucleic acids now claimed are beyond the scope of what is in the prior art. The examiner disagrees. The breadth of "a complement" recited in claims 14 and 29 and "a fragment" and "a biological function" recited in claims 15 – 16 is considerable and is not limited to only those nucleic acids which are complementary over the full length or only those nucleic acids which encode sodium channels.

8. Claims 14 – 19, 23 – 24, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Noda (1986. Nature 320:188 – 192), as evidenced by sequence alignment for NCBI Accession number X03638.

This rejection stands with respect to claims 14 – 19 for the reasons of record and is extended to claims 23 – 24 and 29 as explained herein. Briefly, Noda teaches nucleic acid sequences encoding rat sodium channels. These would be expected to have "a biological function" of a sodium channel as recited in claims 15 – 16 and "a sodium channel function" as recited in claim 23. The sequence alignment mailed with the previous office action indicates that there are many stretches of identity including for example from residues 2270 – 2300 and from 2680 – 2710. Thus the sequence from Noda comprises "a fragment" which encodes a protein that has sodium channel activity and also comprises "a complement", thereby anticipating claims 14 – 16 and 29 (note that Noda specifically teaches cDNAs, which are double-stranded, and therefore necessarily comprise the complements). Claims 17 – 19 are rejected as the reference also teaches vectors. Claim 24 is rejected as it depends from claim 14 and has no additional structural requirements. Absent evidence to the contrary, the "associated with" limitation appears to be provided for.

Applicant argues, on p. 11 of the remarks, that the nucleic acids now claimed are beyond the scope of what is in the prior art. The examiner disagrees. The breadth of "a

complement" recited in claims 14 and 29 and "a fragment" and "a biological function" recited in claims 15 – 16 is considerable and is not limited to only those nucleic acids which are complementary over the full length or only those nucleic acids which encode sodium channels.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14 – 24 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noda (1986. Nature 320:188 – 192) in view of Wang (1997. J Clin Invest 99:1714-1720).

The reasons why claims 14 – 19, 23 – 24, and 29 are anticipated by Noda are set forth above. Briefly, Noda teaches nucleic acids that are within the scope of claims 14 – 16, as well as vectors containing said nucleic acids. However Noda does not teach a cell harboring said vector, as recited in claims 20 – 22.

Wang teaches transfecting vectors comprising nucleic acids encoding sodium channels into cells, which is on point to claims 17 – 19 (vectors) and 20 – 22 (host cells; see p. 1715, Methods). Wang teaches that putting vectors comprising nucleic acids which encode sodium channels is useful for screening for drugs which for treating congenital long QT syndrome. However Wang does not teach the nucleic acid sequences of the invention, as recited in claims 14 – 16.

It would have been obvious to one of ordinary skill in the art to transfect the vectors from Noda into cells, as taught by Wang, thereby arriving at the invention of claims 20 – 22. The motivation to do so would be to screen for anti-arryhthmic drugs, and flows directly from the references themselves.

Applicant argues, on p. 11 of the remarks, that neither the reference by Noda or by Wang teaches nucleic acids encompassed by claims 14 – 16. However as pointed out above, the nucleic acids disclosed by Noda in fact anticipate claims 14 – 16. Thus the rejection under 35 USC § 103 stands for the reasons of record. Applicant did not traverse the examiner's argument that it would have been obvious to one of ordinary skill in the art to transform cells given vectors comprising the appropriate nucleic acid.

***Rejections and Objections Necessitated by Amendment***

***Claim Rejections - 35 USC § 112***

10. Claims 25 – 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant states, on p. 8 of the remarks, that support for new claims 25 – 28 can be found at pages 52 and 54 – 57 of the specification as well as in Figure 3. While the examiner is able to find support for the A565T mutation (p. 55 line 14 for example), the three specific mutations recited in claim 25 parts (a) – (c) and 26 – 28 do not appear within these pages. While Figure 3 indicates certain changes, no residue numbers corresponding to SEQ ID NO:1 are present. Thus the specific mutations in claims 25 – 28 are new matter. Additionally, the examiner is unable to find disclosure of purified nucleic acids with more than one mutation in SEQ ID NO:1, i.e. claim 25, part(d). Thus claim 25 constitutes new matter for this reason as well.

Should applicant disagree with the examiner's determination, applicant should point out those particular places in Figure 3 or in pages 52 and 54 – 57 which disclose the subject matter now claimed. Particularly, applicant should point out where each of the mutations is disclosed, as well as where nucleic acids comprising "any combination of" said mutations, as recited in claim 25 part(d), is disclosed.

Applicant states, on p. 8 of the remarks, that support for claim 29 can be found in the specification at Figure 2 and in the sequence listing. After a careful review of these locations and search of the originally-filed disclosure, the examiner is unable to find contemplation or description of "a nucleic acid having at least 119 contiguous bases of SEQ ID NO:1". Therefore, the examiner has determined that the sub-genus now claimed, i.e. nucleic acids at least 119 bases long, is new matter.

Should applicant disagree with the examiner's determination, applicant should point out those particular places in Figure 2 or the sequence listing which show the genus of nucleic acids which are within SEQ ID NO:1 and are at least 119 bases long.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 – 15, 17 – 18, 20 – 21, and 23 – 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of claim 14 is confusing. On the one hand, the preamble of the claim requires that the claimed nucleic acid encode a sodium channel subunit. However, part (b), newly added by amendment, includes nucleic acids which are complementary to disclosed SEQ ID NO:1. As SEQ ID NO:1 encodes a sodium channel subunit, the complement of that sequence would not be expected to also encode a sodium channel subunit. Thus it is unclear whether applicant is trying to claim only those nucleic acids which encode sodium channel subunits, as recited in the preamble, or also those molecules which are complementary to such subunits, as recited in claim 14 part (b). The remaining claims depend directly or ultimately from claim 14 but do not resolve this ambiguity.

Claim 15 is also confusing as it requires that the alpha subunit of a sodium channel, which is protein, comprise SEQ ID NO:1, which is nucleic acid.

The term "is associated with" in claim 24 is a relative term which renders the claim indefinite. The term "is associated with" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The skilled artisan could not determine which nucleic acids are within the scope of the claim, as it is unclear what it means for the nucleic acid to be "associated with" the increased susceptibility. This aspect of the rejection might be overcome if the language were changed to "wherein the presence of the nucleic acid indicates the subject has an increased risk of idiopathic generalized epilepsy." However, applicant should ensure that any amendments to clarify the scope of the claims are fully supported in the disclosure as originally filed in order to avoid a rejection for recitation of new matter.

***Priority***

12. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or

more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/167623, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The examiner is unable to find disclosure of mutations at positions 828, 3978, 5581, or combinations of these mutations, as recited in new claim 25, in the provisional application. The remarks submitted with the instant claim amendments indicate support can be found at certain pages of the instant specification, but these do not correspond to the same pages of the provisional application. Furthermore, the examiner is unable to find support for nucleic acids which comprise more than one mutation, as recited in claim 25 part(d), in the provisional application. Furthermore, the examiner is unable to find support in the provisional application for the specific mutations recited in claims 26 – 28.

The disclosure of the prior-filed application, Application No. 09/718355, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

The reasons why claims 25 – 29 do not find support in the instant specification are set forth in the rejection for new matter (paragraph number 10) above. As the instant application is a division of 09/718355, the disclosures are identical. Since the claims are not supported by the instant specification, they cannot be supported by the earlier-filed specification either.

Therefore, for the purposes of applying art, the effective filing date of new claims 25 – 29 17 September 2003, the date the instant application was filed. Should applicant disagree with the examiner's factual determination above, applicant should present evidence that either 09/718355, 60/167623, or both in fact disclose every limitation of the claims. This could be accomplished, for example, by pointing out the specific page and line numbers which disclose the mutations in claims 26 – 28, the nucleic acids comprising multiple mutations (i.e. claim 25

part(d)) and the genus of nucleic acids "having at least 119 contiguous bases of SEQ ID NO:1" as recited in claim 29.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene Catalog (1991, p. 66).

Stratagene teaches a product for generating probes to hybridize to DNA sequences. The kit contains random 9-mers that are complementary to all possible DNA sequences 9 nucleotides long. As claims 14 and 29 both encompass "a complement of" SEQ ID NO:1, with no upper or lower bound on the length of the sequence, and the prior art reference teaches all possible 9-mer sequences, it fairly meets the limitations of claims 14 and 29. Note that the Stratgene product comprises all possible 9-mers, and that claims 14 and 29 both use open ("comprising") claim language.

14. Claims 14, 16, 23, and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Furness (U.S. Patent 6,673,549, issued 6 January 2004, filing date 12 October 2001). Applicant is reminded the effective filing date for claim 29 is 17 September 2003.

Furness teaches SEQ ID NO:361. Nucleotides 4874 – 7305 of applicant's SEQ ID NO:1 are identical to nucleotides 59 – 2490 of Furness's SEQ ID NO:361, with the exception of a single base at approximately number 7000, using applicant's numbering scheme; see enclosed alignment. There are over 2000 consecutive nucleotides which are identical. Thus the prior art sequence comprises at least 119 consecutive bases, as recited in SEQ ID NO:1. The sequence

from Furness comprises a complement of SEQ ID NO:1, even though it does not comprise the full-length complement. Thus the reference anticipates claim 14. The specification discloses that SEQ ID NO:1 encodes SEQ ID NO:3, and since the sequence from Furness comprises fragments identical to applicant's SEQ ID NO:1, it necessarily encodes fragments of SEQ ID NO:3. While the sequence is not explicitly identified as encoding an alpha subunit of a sodium channel as recited in claim 29 or one with sodium channel activity as recited in claim 23, these properties appear to be provided given that the sequence in fact has every structural element recited in claims 14 and 29.

***Conclusion***

15. No claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DK

Daniel E. Kolker, Ph.D.
March 28, 2007

RCH

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER

Attachment: sequence alignments

Alignment between applicant's SEQ 1 and Furness's SEQ ID NO:361

<!--StartFragment-->RESULT 1
US-09-976-594-361
; Sequence 361, Application US/09976594
; Patent No. 6673549
; GENERAL INFORMATION:
; APPLICANT: Furness, Michael
; APPLICANT: Buchbinder, Jenny
; TITLE OF INVENTION: GENES EXPRESSED IN C3A LIVER CELL CULTURES TREATED WITH STEROID
; FILE REFERENCE: PA-0041 US
; CURRENT APPLICATION NUMBER: US/09/976,594
; CURRENT FILING DATE: 2001-10-12
; PRIOR APPLICATION NUMBER: 60/240,409
; PRIOR FILING DATE: 2000-10-12
; NUMBER OF SEQ ID NOS: 1143
; SOFTWARE: PERL Program
; SEQ ID NO 361
; LENGTH: 2490
; TYPE: DNA
; ORGANISM: Homo sapiens
; FEATURE:
; NAME/KEY: misc_feature
; OTHER INFORMATION: Incyte ID No. 6673549 1095192.1
US-09-976-594-361

Query Match 27.8%; Score 2330; DB 3; Length 2490;
Best Local Similarity 99.9%; Pred. No. 0;
Matches 2430; Conservative 0; Mismatches 2; Indels 0; Gaps 0;

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Qy       4874 TCGTAACCAGACAAGTTTTTGACATAAGCATCATGATTCTCATCTGTCTTAACATGGTCA 4933
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Db         59 TCGTAACCAGACAAGTTTTTGACATAAGCATCATGATTCTCATCTGTCTTAACATGGTCA 118

Qy       4934 CAATGATGGTGGAAACAGATGACCAGAGTGAATATGTGACTACCATTTTGTCACGCATCA 4993
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Qy       4994 ATCTGGTGTTCATTGTGCTATTTACTGGAGAGTGTGTACTGAAACTCATCTCTCTACGCC 5053
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Qy       5054 ATTATTATTTTACCATTGGATGGAATATTTTTGATTTTGTGGTTGTCATTCTCTCCATTG 5113
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Qy       5234 GCACGCTGCTCTTTGCTTTGATGATGTCCCTTCCTGCGTTGTTTAACATCGGCCTCCTAC 5293
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Qy       5834 TGAGTGGTGACCGGATCCACTGTCTTGATATCTTATTTGCTTTTACAAAGCGGGTTCTAG 5893
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Qy       6134 AAGACATGATAATTGACAGAATAAATGAAAACTCTATTACAGAAAAAACTGATCTGACCA 6193
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Qy       6254 ATGAGCAAGAAGGCAAAGATGAAAAAGCCAAAGGGAAATAAATGAAAATAAATAAAAATA 6313
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